

## **REMARKS**

### **Status of the Claims**

Claims 10, 12, 13, 15-20 and 23 are currently pending in the application. Claims 1, 10, 12, 13, 15-20, 23 and 24 stand rejected. The Examiner objects to claim 23. Claims 10, 12, 13, 15-18 and 23 have been amended as set forth herein. Claims 1 and 24 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendments to claim 23 are merely clarifying amendments which are suggested by the Examiner. Amendments to claims 10, 12, 13 and 15-18 are to change dependency to claim 23. Reconsideration is respectfully requested.

### **ENTRY OF AMENDMENTS**

The amendments to the claims should be entered by the Examiner because the amendments are supported by the as-filed specification and do not add any new matter to the application. Additionally, the amendments should be entered since they comply with requirements as to form, and place the application in condition for allowance. Further, the amendments do not raise new issues or require a further search since the amendments incorporate elements from dependent claims into independent claims and/or are supported by the as-filed specification. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

### **Interview**

Applicants and Applicants' representatives thank the Examiner for extending the courtesy of an interview on or about March 21, 2008. The substance of the interview is substantially as reflected in the Interview Summary of April 1, 2008. Briefly, during the interview, all issues barring allowance of the present claims were discussed. Specifically, the disclosures of the cited references were discussed as well as the fact that Tomida et al. is directed to electrophoresis, which purification method is different from the presently claimed purification methods. Applicants submit herein the claim amendments proposed by the Examiner at pages 10-11 of the Office Action of January 7, 2008 for entry into the record and consideration by the Examiner. Reconsideration and allowance of all pending claims are therefore respectfully requested.

### **Objections to the Claims**

The Examiner objects to claim 23. The Examiner states that claim 23 recites various grammatical errors at lines 8 and 15. To expedite prosecution, claim 23 has been amended as the Examiner suggests to address the grammatical errors.

Reconsideration and withdrawal of the objection to claim 23 are respectfully requested.

### **Rejections Under 35 U.S.C. § 103(a)**

Kitos et al., Tomida et al. & Tsao et al.

Claims 1, 10, 16 and 17 stand rejected as being unpatentable over Kitos et al., *Biochemistry*, 12(25):5086-5091, 1973 (hereinafter, "Kitos et al.") in view of Tomida et al., *FEBS Lett.*, 334(2):193-197, 1993 (hereinafter, "Tomida et al.") and Tsao et al., U.S. Patent No.

4,090,022 (hereinafter, "Tsao et al."). (*See*, Office Action of January 7, 2008, at pages 4-6, hereinafter, "Office Action"). Claim 1 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection of claim 1. Applicants traverse the rejection as to the remaining claims.

The Examiner states that Kitos et al. disclose adsorbing nucleic acid to a solid phase of cellulose wherein the nucleic acid solution contains nucleic acids of different lengths. The Examiner states that Kitos et al. also disclose the steps of washing and eluting the adsorbed nucleic acids thereby purifying a nucleic acid from a mixture of nucleic acids comprising poly(A) and poly (U). The Examiner admits Kitos et al. do not disclose or suggest chromatography of nucleic acids using cellulose media in a column having two openings or adsorbing nucleic acids of 10 kb or longer.

The Examiner cites to Tomida et al. to find motivation to purify nucleic acids having a length of 10 kb or longer (by electrophoresis).

The Examiner also admits that neither Tomida et al. nor Kitos et al. disclose or suggest the use of triacetylcellulose having a surface saponification rate of 10-100% or a pore size of 0.1  $\mu\text{m}$  to 10  $\mu\text{m}$ . To find these missing limitations, the Examiner cites to a third reference, Tsao et al. The Examiner states that Tsao et al. disclose beads of cellulose triacetate having a pore size within the range of pore sizes presently claimed.

Finally, the Examiner states that there is motivation to combine the various limitations of all three of these references because Tsao et al. disclose that the cellulose triacetate beads offer enhanced flow properties and the methods of Kitos et al. require fluid flow to purify the nucleic

acids. Furthermore, the Examiner states that Tomida et al. provides motivation to purify nucleic acids having a size of 10 kb or larger.

Although Applicants do not agree that the Examiner has adequately established a *prima facie* case of obviousness in combining the three cited references, to expedite prosecution, Applicants have cancelled claim 1 and amended claims 10, 16 and 17 to depend from non-obvious claim 23. Therefore, it is believed that claims 10, 16 and 17 are non-obvious for, *inter alia*, depending from a non-obvious base claim, amended claim 23.

Reconsideration and withdrawal of the obviousness rejection of claims 10, 16 and 17 are respectfully requested.

Kitos et al., Tomida et al., Tsao et al. & Woodard et al.

Claims 12, 15 and 18 stand rejected as being unpatentable over Kitos et al. in view of Tomida et al., Tsao et al., and further in view of Woodard et al., EP 0512767 (hereinafter, "Woodard et al."). (See, Office Action, at pages 6-8). Applicants traverse the rejection.

In addition to the comments provided above concerning Kitos et al., Tomida et al. and Tsao et al., the Examiner states that Woodard et al. disclose treating a sample containing a cell or a virus with nucleic acid solubilizing reagent (lysis buffer) and adding an aqueous organic solvent to the solution. The Examiner also states that Woodard et al. disclose a washing buffer containing 50% ethanol and pulling liquid through a membrane. The Examiner states that motivation exists to combine all four of the cited references in exactly the manner stated because Woodard et al. shows that such methods may be used to successfully purify nucleic acids and because Kitos et al. disclose that such nucleic acids may be purified from cellular sources.

Although Applicants do not agree that the Examiner has adequately established a *prima facie* case of obviousness in combining the four cited references, to expedite prosecution, Applicants have amended claims 12, 15 and 18 to depend from non-obvious claim 23. Therefore, it is believed that claims 12, 15 and 18 are non-obvious for, *inter alia*, depending from a non-obvious base claim, amended claim 23.

Reconsideration and withdrawal of the obviousness rejection of claims 12, 15 and 18 are respectfully requested.

Kitos et al., Tomida et al., Tsao et al., Woodard et al. & Benjamin et al.

Claim 13 stands rejected as being unpatentable over Kitos et al. in view of Tomida et al., Tsao et al. and Woodard et al. and in further view of Benjamin et al., U.S. Patent No. 5,695,946 (hereinafter, "Benjamin et al."). (See, Office Action, at pages 8-9). Applicants traverse the rejection.

In addition to the comments provided above, concerning Kitos et al., Tomida et al., Tsao et al. and Woodard et al., the Examiner states that Benjamin et al. disclose release of target nucleic acids from cells by treatment of the cells with various reagents including guanidine salts, proteinase K and detergents.

Although Applicants do not agree that the Examiner has adequately established a *prima facie* case of obviousness in combining the five cited references, to expedite prosecution, Applicants have amended claim 13 to depend from non-obvious claim 23. Therefore, it is believed that claim 13 is non-obvious for, *inter alia*, depending from a non-obvious base claim, amended claim 23.

Reconsideration and withdrawal of the obviousness rejection of claim 13 are respectfully requested.

Kitos et al., Tomida et al., Tsao et al., Woodard et al. & Heath

Claims 19 and 20 stand rejected as being unpatentable over Kitos et al. in view of Tomida et al., Tsao et al. and Woodard et al., and further in view of Heath, WO 99/13976 (hereinafter, "Heath"). (See, Office Action, at pages 9-10). Applicants traverse the rejection.

In addition to the comments provided above concerning Kitos et al., Tomida et al., Tsao et al. and Woodard et al., the Examiner states that Heath discloses automated methods of isolation of nucleic acids from samples by loading the samples into a container having at least two openings, washing the media inside the container, and eluting the nucleic acids with the use of a vacuum pump. The Examiner states that Heath discloses loading of the nucleic acid samples by aspiration using a negative pressure to suck the sample into the chamber.

Although Applicants do not agree that the Examiner has adequately established a *prima facie* case of obviousness in combining the five cited references, to expedite prosecution, Applicants have amended claim 18 to depend from non-obvious claim 23. Therefore, it is believed that claims 19 and 20, through their dependency on amended claim 18, are non-obvious for, *inter alia*, indirectly depending from a non-obvious base claim, amended claim 23.

Reconsideration and withdrawal of the obviousness rejection of claim 19 and 20 are respectfully requested.

**Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1, 10, 12, 13, 15-20, 23 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at pages 10-19). Claims 1 and 24 have been cancelled without prejudice or disclaimer, thus obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as follows.

The Examiner states that the claims encompass separation and purification of nucleic acids of 10 kb or longer from a sample solution comprising nucleic acids of different lengths, encompassing nucleic acids of any size including very long nucleic acids and very short nucleic acids. The Examiner maintains that “the required separation steps of the claims do not appear consonant with the teachings of the specification.” (*Id.* at page 19). However, the Examiner has provided at pages 10-11 of the Office Action a proposed claim 23 which is stated to not lack enablement.

Although Applicants maintain their disagreement with the Examiner and fully believe the present specification adequately enables one of skill in the art to practice the claimed invention, to expedite prosecution, claim 23 has been amended to be consistent with the proposed claim 23 suggested by the Examiner. All other dependent claims have been amended to depend, either directly or indirectly, from amended claim 23. Thus, as indicated by the Examiner, all pending claims, as amended, are adequately enabled by the present specification.

Therefore, reconsideration and withdrawal of the enablement rejection of claims 10, 12, 13, 15-20 and 23 are respectfully requested.

### CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: April 7, 2008

Respectfully submitted,

By 

Marc S. Weiner  
Registration No.: 32,181  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicants